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### **Remarks**

This paper responds to the first Office action in the above-entitled application, mailed March 29, 2007, and allowing three months for a response. This response is timely because an extension of the time for response (2 months) is being filed with this paper.

The applicant will address all the points raised by the Examiner and demonstrate that claims 1-3 and 5-7 are patentable for the reasons provided below.

### **Priority**

The suggestion to claim priority of PCT/US02/28970 (Alford et al.), filed September 12, 2002, is appreciated. However, the proposed priority application does not have any inventor in common with the present application, so a claim of priority is not believed to be appropriate.

### **35 U.S.C. § 102 (Novelty) – Akio**

The applicant has been asked to show that claims 1, 4, and 5 in this case are novel compared to the Akio reference. The applicant respectfully submits that claims 1 and 5 are novel because the present claims and the prior art differ. (Claim 4 has been canceled.)

Claim 1 and its dependent claim 5 are distinguished from the Akio reference because claim 1 recites “a time-release free radical scavenger,” which the Akio reference does not teach. In Akio, the adenosine is dissolved, and thus not maintained in time-release form.

Claims 1 and 5 are therefore novel.

### **35 U.S.C. § 102 (Novelty) – Polyak et al.**

Claim 4 has been canceled, without prejudice.

### **35 U.S.C. § 103 (Non-obviousness) – Polyak et al. v. Rath et al.**

The applicant has been asked to show that claim 6 in this case is non-obvious in view of the Polyak et al. and Rath et al. references. The applicant respectfully submits that claim 6 is non-obvious, for the reasons provided below.

Claim 6 recites a time-release composition, which the Polyak et al. reference does not disclose (as the Office action indicates). The Polyak et al. reference discloses “solutions” comprising adenosine, which thus is apparently dissolved. The rejected claim is therefore novel, notwithstanding the Polyak et al. reference.

Claim 6 recites “a free radical scavenger in time-release form,” which the Rath et al. reference does not disclose. The Rath et al. reference at col 6, lines 23-27, contains a brief boilerplate disclosure of a time release composition to administer an ascorbate or a binding inhibitor *in vivo* for a therapeutic purpose, not to deploy a free radical scavenger to maintain an ex vivo organ. The rejected claims are therefore novel, notwithstanding the Rath et al. reference.

It would not be obvious to combine the Polyak et al. and Rath et al. references to arrive at the present invention. No reason is shown why one of ordinary skill in the art would modify the Polyak et al. reference as the Office action proposes, to modify its free radical scavenger solution into time release form. The Rath et al. reference is not pertinent to the problems addressed when maintaining an ex vivo organ. Also, neither reference suggests that a free radical scavenger even can be provided in time-release form. Obviousness cannot be established merely by finding each element of the invention individually in the prior art. The only apparent reason for combining these references would be hindsight, which is not appropriate.

**35 U.S.C. § 103 (Non-obviousness) – Polyak et al. v. Rath et al. and Chien et al.**

The applicant has been asked to show that claim 7 in this case is non-obvious in view of the Polyak et al., Rath et al. and Chien et al. references. The applicant respectfully submits that claim 7 is non-obvious, for the reasons provided below.

Polyak et al. and Rath et al. have been distinguished above.

Chien also does not disclose the use of a time release technology to distribute an antioxidant or to maintain an ex vivo organ, and also does not relate to the present problem, which is how to preserve an organ ex vivo. Thus, adding Chien et al. does not overcome the shortcomings of the other prior art cited by the Examiner.

**35 U.S.C. § 103 (Non-obviousness) – Akio v. Rath et al.**

The applicant has been asked to show that claims 2 and 6 in this case are non-obvious in view of the Akio and Rath et al. references. The applicant respectfully submits that these claims are non-obvious, for the reasons provided below.

Claims 2 and 6 are distinguished from the Akio reference because the Akio reference does not teach a time-release free radical scavenger. In Akio, the adenosine is dissolved, and thus not maintained in time-release form.

Claims 2 and 6 are distinguished from the Rath et al. reference because the Rath et al. reference at col 6, lines 23-27, contains a brief boilerplate disclosure of a time release composition to administer an ascorbate or a binding inhibitor *in vivo* for a therapeutic purpose, not to administer a free radical scavenger. The rejected claims are therefore novel, notwithstanding the Rath et al. reference.

It would not be obvious to combine the Akio and Rath et al. references to arrive at the present invention. No reason is shown why one of ordinary skill in the art would modify the Akio et al. reference as the Office action proposes, to provide its free radical scavenger solution in time release form. Neither applied reference recognizes any need to provide the free radical scavenger of Akio in time release form. The Rath et al. reference also is not pertinent to the problem addressed by the present invention of maintaining an *ex vivo* organ. Also, neither reference suggests that a free radical scavenger even can be provided in time-release form. Obviousness cannot be established merely by finding each element of the invention individually in the prior art.

Claims 2 and 6 are therefore non-obvious in view of the cited prior art.

**35 U.S.C. § 103 (Non-obviousness) – Akio v. Rath et al. and Chien et al.**

The applicant has been asked to show that claims 3 and 7 in this case are non-obvious in view of the Akio, Rath et al., and Chien et al. references. The applicant respectfully submits that these claims are non-obvious, for the reasons provided below.

Claims 3 and 7 are distinguished from the Akio reference because the Akio reference does not teach a time-release free radical scavenger. In Akio, the adenosine is dissolved, and thus not maintained in time-release form.

Claims 3 and 7 are distinguished from the Rath et al. reference because the Rath et al. reference at col 6, lines 23-27, contains a brief boilerplate disclosure of a time release composition to administer an ascorbate or a binding inhibitor *in vivo* for a therapeutic purpose, not to administer a free radical scavenger. The rejected claims are therefore novel, notwithstanding the Rath et al. reference.

Chien also does not disclose the use of a time release technology to distribute an antioxidant, and also does not relate to the present problem, which is how to preserve an organ *ex vivo*. Thus, adding Chien et al. does not overcome the shortcomings of the other prior art cited by the Examiner.

It would not be obvious to combine the Akio, Rath et al, and Chien et al. references to arrive at the present invention. No reason is shown why one of ordinary skill in the art would modify the Akio et al. reference as the Office action proposes, to provide its free radical scavenger solution in time release form. No reference applied in this rejection recognizes any need to provide the free radical scavenger of Akio in time release form. The Rath et al. and Chien et al. references also are not pertinent to the problem addressed by the present invention of maintaining an *ex vivo* organ. Also, none of the references applied here suggests that a free radical scavenger even can be provided in time-release form. Obviousness cannot be established merely by finding each element of the invention individually in the prior art. The only apparent reason for combining these references would be hindsight, which is not appropriate.

Claims 3 and 7 are therefore non-obvious in view of the cited prior art.

### **35 U.S.C. § 132 (Amendments Supported)**

The amendments to claims 1 and 2 reciting time release are supported by original claim 6, for example. The amendments in this paper are therefore free of new matter.

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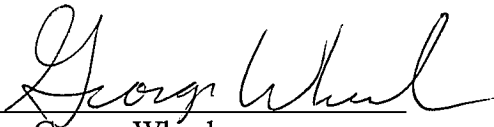
**Conclusion**

The applicant has shown that this application satisfies all the legal requirements pointed out by the Examiner. Therefore, the Examiner is respectfully requested to prepare a Notice of Allowability allowing all the pending claims (1-3 and 5-7).

Please charge any fees required in connection with this filing or credit any overpayment of fees to McAndrews, Held & Malloy Deposit Account No. 13-0017.

Respectfully submitted,

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